

PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

Applicant's or agent's file reference GRA3189PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/014147	International filing date (day/month/year) 13.12.2004	Priority date (day/month/year) 12.12.2003
International Patent Classification (IPC) or national classification and IPC C08J5/18, C08J3/24, A61K9/00, A61K9/70, C08B15/00		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG etc		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 5 sheets, including this cover sheet.
3.	<p>This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>
4.	<p>This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement according to Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand 30.09.2005	Date of completion of this report 29.12.2005
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Box No. I. Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language insert language, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b)).
 - ☐ publication of the international application (under Rule 12.4).
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3).
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, pages

1-21 as originally filed

Claims, No.

1-9 received on 06.12.2005 with the letter of 02.12.2005

- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)):
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-4
	No:	Claims	5-9
Inventive Step (IS)	Yes:	Claims	
	No:	Claims	1-9
Industrial Applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations (Rule 70.7)**Insert text here**

Re box V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: US-B1-6 375 963 (REPKA MICHAEL A ET AL) 23 April 2002 (2002-04-23)
- D2: WO 99/55312 A (VIROTEX CORPORATION) 4 November 1999 (1999-11-04)
- D3: WO 98/22097 A (BIO ADVANCES, LLC) 28 May 1998 (1998-05-28)
- D4: WO 01/58430 A (NATIONAL STARCH AND CHEMICAL INVESTMENT HOLDING CORPORATION) 16 August 2001 (2001-08-16)
- D5: EP-A-0 410 696 (E.R. SQUIBB & SONS, INC) 30 January 1991 (1991-01-30)
- D6: WO 03/063839 A (NATIONAL STEEL CORPORATION; UNIVERSITEIT UTRECHT; NATIONAL STARCH AND) 7 August 2003 (2003-08-07)
- D7: DE10146251 A1 (2003-04-17), mentioned in the application.

1. The subject matter of claims 5 to 9 in the application is not novel (PCT Article 33(2)) in view of the optionally multilayer dosage forms in film form which are disclosed in documents D1 to D6 and comprise an active ingredient-containing layer composed of a polyacrylic acid derivative and of a polysaccharide such as, for example, hydroxypropyl(methyl)cellulose or hydroxyethylcellulose, with at least partial crosslinking between the polyacrylic acid derivative and the polysaccharide naturally taking place during the production thereof (see the passages of text mentioned in the search report). It should further be noted that a product does not become novel simply by being produced by a different process.

2. The subject matter of claims 1 to 4 is obvious (PCT Article 33(3)) from the routine use of previously disclosed devices (see D7, figure 4 and claim 10) in which a two-component nozzle allowing simultaneous spraying of different solutions of polymers and crosslinkers is used in the production of optionally multilayer dosage forms in film form by spraying, as disclosed in documents D2, D3 or D4. It should further be

noted that the only comparative test in the application uses just such a device, and thus the object of the application can only be to provide further good processes for producing dosage forms in film form. The application contains no evidence which might substantiate the achievement of a more demanding object (e.g, providing an improved process for producing a dosage form in film form) compared with the disclosed prior art.